K024302

510(k) Summary
for
Precision Capillaries for Micromanipulation

FEB 1 9 2003

1. SPONSOR

Brinkmann Instruments, Inc.
One Cantiague Road
P.O. Box 1019
Westbury, NY 11590-0207

Contact Person: Joel Lopez
Telephone: 516-515-2396

Date Prepared: December 23, 2002

2. DEVICE NAME

Proprietary Name: Precision Capillaries for Micromanipulation
Common/Usual Name: Microcapillaries
Classification Name: Assisted Reproduction Microtools

3. PREDICATE DEVICES

- Scan-Med, Inc. (K991700), Swemed Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes
- Humagen Fertility Diagnostics, Inc. (K990847), Intracytoplasmic Sperm Injection Micropipets (ICSI), Spermatid ICSI Micropipets, Holding Micropipets, Assisted Hatching Micropipets, Subzonal Injection Micropipets (SUZI), Partial Zona Dissection Micropipets (PZD), Denuding Micropipets
- Prodimed (K983713), Prodimed Microinjection Pipettes
- Cook OB/GYN (K983596), Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching /Zona Drilling Pipettes

4. DEVICE DESCRIPTION

The proposed Precision Capillaries for Micromanipulation (Precision Capillaries) product line contains the following types of microcapillaries:

- VacuTips Holding Capillary, used for holding human oocytes, blastocysts, or other suspension cells
- TransferTips® (ICSI), used for transferring sperm and perforating oocytes using the ICSI (Intracytoplasmic Sperm Injection) technique

5. INTENDED USE

The Precision Capillaries are microcapillaries intended for the following uses in assisted reproduction procedures:

- Holding human oocytes, blastocysts, or other suspension cells
- Transferring and injecting sperm (or cells of a similar size) using the ICSI (Intracytoplasmic Sperm Injection) technique

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Precision Capillaries and the substantially equivalent devices are borosilicate glass microcapillaries designed for use in assisted reproduction procedures. The proximal end of the shaft is inserted into the capillary holder of the micromanipulator or microinjector. The distal end is drawn to a narrow tip that contacts the gamete for transfer and/or perforation. The distal end of the VacuTips is blunt for cell transfer. The TransferTips (ICSI) have spiked tips for perforation of the gamete. Three forms of the TransferTips (ICSI) are described in the 510(k), TransferTips-F, TransferTips-R, and TransferTips-RP. The TransferTips vary in shaft length, tip length, and flexibility of the flange.

Each Precision Capillary is mounted in a "Capillary Safe" consisting of a holder and protective tube to protect the capillary and the user during transport and handling. The Precision Capillary mounted in the Capillary Safe is sealed in a foil pouch to maintain sterility. The packaged devices are sterilized by gamma irradiation.

Differences between the proposed and predicate devices are limited to minor differences in design such as the length of the shaft, tip angle, the inner and outer

diameter of the tip, and the presence of a spike. These differences are minor and do not raise any new issues of safety or effectiveness.

7. PERFORMANCE TESTING

Biological and functional testing conducted to evaluate the safety and efficacy of the Precision Capillaries for their uses in assisted reproduction procedures includes bioburden determination, endotoxin determination, embryotoxicity testing, application testing, and packaging evaluation. The test data obtained from these testing programs indicate that the Precision Capillaries are non-embryotoxic and non-pyrogenic. The Precision Capillaries successfully aspirated sperm and easily perforated oocytes. These results demonstrate that the Precision Capillaries are safe and effective for their uses in assisted reproduction procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Brinkmann Instruments, Inc.
% Cynthia J. M. Nolte, Ph.D.
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K024302
Trade/Device Name: Precision Capillaries for Micromanipulation
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: 85 MQH
Dated: December 23, 2002
Received: December 24, 2002

Dear Dr. Notle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K024302

510(k) Number (if known): K024302

Device Name: Precision Capillaries for Micromanipulation

Indications for Use:

The Precision Capillaries for Micromanipulation are microcapillaries intended for the following uses in assisted reproduction procedures:

- Holding human oocytes, blastocysts, or other suspension cells
- Transferring and injecting sperm (or cells of a similar size) using the ICSI (Intracytoplasmic Sperm Injection) technique

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024302

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)